NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

NOTICE OF SUPPLEMENTAL PROPOSED EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

Editor's Note: The following Notice of Supplemental Proposed Exempt Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2577.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 9, 2011.

[R11-194]

PREAMBLE

1. Citations to the agency's Notice of Rulemaking Docket Opening, the Notice of Proposed Rulemaking, and any other Notices of Supplemental Proposed Rulemaking (if applicable) as published in the *Register* as specified in R1-1-409(A). A list of any other related notices published in the *Register* to include the as specified in R1-1-409(A):

Notice of Proposed Exempt Rulemaking: 17 A.A.R. 2068, October 14, 2011

2. Articles, Parts, or Sections Affected (as applicable)Rulemaking Action:

R9-22-710 Amend

3. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 36-2903.01, 36-2907

Implementing statute: A.R.S. § 36-2904

Statute or session law authorizing the exemption: Laws 2011, Ch. 31, § 34

4. The agency's contact person who can answer questions about the rulemaking:

The original close of the comment period ended October 23, 2011. As a result of the comments received by October 23, 2011, the AHCCCS Administration has amended the proposed rulemaking and encourages the public to review and submit comments again by January 2, 2012.

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5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

The Veterans Health Care Act of 1992 established the 340B program in section 340B of the Public Health Service Act (PHS Act) codified as 42 U.S.C. 256b. The 340B program requires the Secretary of the United States Department of Health and Human Services (U.S. DHHS) to enter into agreements with drug manufacturers to provide a specified discount for outpatient drugs sold to certain eligible health care entities, known as covered entities if those drugs are paid for through the Medicaid program. Covered entities include disproportionate share hospitals, family planning

clinics, and federally qualified health centers, among others as described under 42 U.S.C. 256b(a)(4). As of October 2010, approximately 15,000 covered-entity locations were enrolled in the 340B program.

The Health Resources and Services Administration (HRSA) within the U.S. DHHS administers the 340B program. In 2000, HRSA issued guidance directing covered entities to refer to State Medicaid agencies' policies for applicable billing policies in regards to reimbursement of claims for dispensing 340B drugs. The Centers for Medicare and Medicaid Services (CMS), which administers the Medicaid program, encourages State Medicaid agencies to set 340B policies. The AHCCCS Administration has chosen to develop a policy and a rule that specify the reimbursement methodology applicable to Federally Qualified Health Centers (FQHCs) and FQHC Look-Alike pharmacies for drugs that are identified in the 340B pricing file whether or not they are purchased under the 340B program. In this rule the AHCCCS Administration has also described the reimbursement applicable to pharmacies that contract with covered entities and dispense 340B drugs. The AHCCCS Administration has submitted a Medicaid State Plan Amendment to CMS that describes the reimbursement methodology set forth in this proposed rule and is awaiting approval from CMS.

In addition, section 1927 of the Social Security Act (42 U.S.C. 1396r-8), established a separate requirement that the Secretary of the U.S. DHHS enter into agreements with drug manufacturers to provide each state Medicaid agency with a rebate for all outpatient drugs paid for through the Medicaid program. To avoid requiring drug manufacturers to provide two discounts – one to the 340B covered entity at the time of purchase, and another in the form of a subsequent rebate to the State Medicaid agency – section 340B(a)(5)(a)(i) of the Public Health Service Act prohibits a 340B covered entity from submitting a claim to the State Medicaid agency for an outpatient drug if payment for that drug is also used by the State Medicaid agency as the basis for claiming a rebate from the drug manufacturer. Under section 1927(a)(5)(C) of the Social Security Act, each covered entity is required to indicate on any claim submitted to the State Medicaid Agency whether the claim is for a drug purchased through the 340B program. The State Medicaid Agency is precluded from submitted the cost of that drug for a rebate from the drug manufacturer.

Under the demonstration project granted by the Secretary under section 1115 of the Social Security Act through October 21, 2011, the Arizona Medicaid Program (AHCCCS) did not participate in the Federal Medicaid Drug Rebate Program. The reason for not participating in the program and receiving this waiver from CMS was due to the fact that only drugs paid for by state Medicaid agencies were eligible for federal rebates. Drugs provided through the Medicaid Managed Care Organizations (MCOs) were not eligible for rebates through the Medicaid drug rebate program. Only drugs provided to Fee-for-Service (FFS) members by retail and long-term care pharmacies were eligible for Medicaid rebates. Prior to the Patient Protection and Affordable Care Act (PPACA), the costs to administer the federal rebate program for the Fee-for-Service program would have exceeded the revenues generated by the rebates, therefore, the CMS Waiver exempted AHCCCS from participation in the Medicaid drug rebate program even with respect to outpatient drugs provided on a fee-for-service basis.

As of March 23, 2010, the Patient Protection and Affordable Care Act required that outpatient drugs paid for through the Medicaid program, including outpatient drugs paid for by Medicaid managed care organizations, were subject to the Medicaid drug rebate program. The State Medicaid program is required to submit utilization claims data for rebates for drugs provided by contracted MCOs. Currently, AHCCCS works with a contracted Medicaid managed care organizations to obtain rebates on all eligible drugs. However, drugs purchased by covered entities under the 340B pricing program are still not eligible for Medicaid rebates.

Numerous entities are permitted to participate in the 340B program and purchase drugs at these discounted prices. Entities that purchase drugs at 340B pricing are providing those drugs to AHCCCS members and submitting claims to AHCCCS or its Managed Care Contractors and are reimbursed at a discounted retail price negotiated by the Pharmacy Benefit Managers (PBMs). Despite the discounts negotiated by the PBM, the difference between the 340B entity's actual acquisition cost of the drug and the PBM's reimbursement rate is significant and substantial. Currently, the Arizona Medicaid program reimburses the 340B covered entities the same amount that it would have had the drug not been purchased through the 340B program. In essence, the full cost of the discount provided by the drug manufacture to the 340B entity is born by AHCCCS program while at the same time AHCCCS is prohibited from claiming the Medicaid drug rebate for the cost of reimbursing the 340B covered entity.

To address the inability of AHCCCS to claim the Medicaid drug rebate for these drugs and the disparity between actual acquisition cost of drugs in the 340 pricing program dispensed by FQHC and FQHC Look-Alike pharmacies and the current AHCCCS reimbursement rate for those drugs, the AHCCCS Administration is proposing a rule to require a reimbursement methodology specific to 340B drugs dispensed by FQHC and FQHC Look-Alike Pharmacies. In addition, the rule specifies the reimbursement methodology applicable to drugs dispensed by 340B covered entities that are not eligible for purchase under the 340B pricing program and also describes the reimbursement to pharmacies that contract with 340B covered entities to dispense drugs as part of that program. By implementing this methodology, the potential for duplicate discounts will be eliminated, 340B covered entities and pharmacies that contract with them will receive reasonable compensation taking into consideration their reduced acquisition cost, and AHCCCS will not carry the cost of the 340B drug discount federal law imposes on drug manufacturers.

Arizona Laws 2011, Ch. 31, § 34, authorized the agency to adopt rules necessary to implement a program within available appropriations, including making changes to reimbursement rates and methodologies, and to make changes to rules relating to cost sharing responsibilities of eligible persons.

Arizona Laws 2011, Ch. 31, § 34 exempts the Administration from the formal rulemaking requirements of A.R.S. Title 41, Chapter 6.

Arizona Law 2011, Ch. 31, § 34, which authorizes this exempt rulemaking, requires public notice with an opportunity for public comment of at least 30 days. Public notice of this rulemaking will be accomplished through publication of this rulemaking on the agency web site on September 23, 2011. A supplemental notice will also appear in the *Arizona Administrative Register* in advance of the close of the comment period. In addition, notice will be directed to those individuals who, prior to this proposed rulemaking have notified the agency of their desire to receive such notices directly pursuant to A.R.S. § 36-2903.01(B)(6).

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The United States Department of Health and Human Services Office of Inspector General issued a report with the following recommendations: (1) inform states that they should incorporate 340B policies into their Medicaid State Plans, (2) inform states of alternative methods of identifying 340B claims that we identified in this report, and (3) facilitate communication between HRSA and states by providing a list of State Medicaid pharmacy directors to HRSA and instructing states to contact HRSA when errors in the Medicaid Exclusion File are found. CMS and HRSA concurred with the recommendations.

The following sources of information on dispensing costs and fees were reviewed:

(a) Cost of Dispensing Study: An independent comparative analysis of U.S. prescription dispensing costs (2007), by Grant Thornton LLP
(b) GAO reference to results from Study of Medi-Cal Pharmacy Reimbursement (2002), by Myers and Stauffer LC
(c) Survey of Dispensing Costs of Pharmaceuticals in the State of Oregon (2010), by Myers and Stauffer
(d) Development and Testing of a Prescription Drug Benefit Reimbursement Methodology for South Carolina Medicaid (2010), by Michael Dickson, PhD and Dana Stafkey-Mailey, PhD
(e) 340B Pharmacy Dispensing Cost Summary (06/28/2011), data provided by the Arizona Association of Community Health Centers

AHCCCS found these studies and data sources useful to its general understanding of pharmacy costs and operations, and has not relied on any of them in its evaluation of or justification for the rule, except that the study referred to in (d) was the Administration's source for a recommended 340B dispensing fee for the state of South Carolina. The dispensing fee established for reimbursement of 340B purchased drugs is based on 340B dispensing fees for other state Medicaid agencies, adjusting to comparable fee levels for Arizona using geographic practice cost indices and applying an inflation factor where appropriate.

The Administration analyzed AHCCCS claims data at the NDC level for the 1st quarter of 2011. Applying the 340B-specific dispensing fee referred to in item 9 below, the Administration estimates a net saving of $7.1M annually.

The documents referenced above are available and on file with the AHCCCS Administration and can be requested in writing via e-mail or mail through the contact information listed under item 4.

7. An explanation of the substantial change which resulted in the supplemental notice:

After consideration of the comments received the agency has amended the rulemaking to remove "contracted pharmacies" from the rule. The following comments had been received either by mail or mail by the close of the comment period October 23, 2011.

Numb:	Date/ Commentor:	Comment:	Response:
1.	10/19/2011 John McDonald, CEO AACHC	The AHCCCS program has approached the 340B Community Health Centers (CHC) providing services to Medicaid eligible outpatients with the plan to change the reimbursement model to one tied to the entity's drug acquisition plus cost of dispensing (COD) designed to "cover" the organization's cost while removing any positive revenue stream. This proposed AHCCS ruling is being done in conjunction with an effort to have Arizona participate in the federal rebate program and associated efforts to contain AHCCCS programmatic costs. *(sic)*	The Grant Thornton study is one among several information sources viewed by AHCCCS. Section 7 of the preamble has been revised to clarify this. The Cost Of Dispensing (COD) cited by the commenter is identified in that study as the "non-weighted average per pharmacy." AHCCCS has established a per-prescription dispensing fee and believes that, for purposes of comparison to the proposed dispensing fee, a per-prescription statistic is more relevant. AHCCCS also believes that, given the likelihood of outliers in the type of data studied, median is the better measure of central tendency.

Numb:	Date/ Commentor:	Comment:	Response:
1. *continued*		The AHCCCS reimbursement change, while intended to cover 340B entity costs, will not do so at the reimbursement rate of $8.75 for the vast majority of CHC 340B pharmacies. The average cost of dispensing for AACHC 340B pharmacies is $12.28. The COD rate of $8.75 will have the unintended consequence of reducing the ability of organizations to continue their 340B programs and in some cases cause closure of these pharmacy services. The Grant Thornton National Cost of Dispensing (COD) Study Final Report January 26, 2007 referred to by AHCCCS to determine the $8.75 rate for AACHC pharmacies found that the cost is significantly higher. The actual average pharmacy cost of dispensing for Medicaid in the study is $12.81. The $12.81 number is reflective of 2006 data as reported in 2007 Grant Thornton Cost of Dispending Study. Adjusted for CPI physician service annually for 2011 the COD would be $14.82. We would encourage AHCCCS to look at possible ways to expand the availability of 340B services including a more realistic COD reimbursement and possibly shared profits rather than policies that may have the unintended consequence of limiting availability of 340B services making access more challenging and possibly reducing some longer term cost savings to the program.	In viewing the Grant Thornton study, as well as other studies presenting similar information, AHCCCS gave its attention to the median COD per prescription.
2.	10/21/2011 Dave Dederichs, Director Government Affairs Express Scripts, Inc	**Article 7 Section B. Pharmacy services and Section C. FQHC Pharmacy reimbursement. (340B entity)** Currently, there is not a system to identify 340B claims. The definitions of these fields changed recently at the last NCPDP workgroup to state that the fields were only applicable to FFS Medicaid or when required by law or regulation. For this reason, we are concerned that if the State does not mandate these fields be populated, our ability to appropriately identify all 340B drugs is limited. Those fields are: • Basis of Reimbursement Determination field (522-FM) – value of 12 indicates drug was accessed at 340B prices • Basis of cost determination code (423-DN) – value of 8 indicates 340B claim • Compound Ingredient Basis of Cost Determination (490-UE) – value of 8 indicates 340B claim.	In the proposed rule on p. 8, (2)(d), it states: "The 340B drug claim identifier shall be consistent with claim instructions issued and required by AHCCCS to identify such claims." AHCCCS will communicate prescription claims submission requirements, including, but not limited to, the "340B Identifier" and the "Ingredient Cost Submitted" fields to the AHCCCS FFS PBM and to AHCCCS Managed Care Contractors. AHCCCS recognizes that contractors and subcontractors may require a minimum of 30 days to facilitate and implement the rule requirements and will ensure timely notification is provided. The listing of 340B entity pharmacies can be accessed at the HRSA/ Office of Pharmacy Affairs web site, www.hrsa.gov/opa/. The web site contains a link to 340B entity database. AHCCCS will provide a monthly list of the FQHC/FQHC Look-Alike pharmacies to the AHCCCS FFS PBM and AHCCCS Managed Care Contractors.

Numb:	Date/ Commentor:	Comment:	Response:
2. *continued*		Express Scripts cautions the state about the impact of retroactive changes or changes that would result in less than 30 days for implementation. ESI would like to stress the importance of timely and prospective notification of list changes by the state. Recommendation: Express Scripts recommends that the State prospectively maintain the list as necessary, and that updated lists be made readily available to all providers in a timely manner. Express Scripts is concerned that pharmacies may not disclose their 340B acquisition costs per the requirement of this rulemaking. The proposed rule does not explain what data field should be used report the acquisition cost. *(sic)* Recommendation The State should mandate the inclusion of the fields mentioned above (NCPDP transactions set) and require the submission of the 340B price in the Ingredient Cost Submitted fields. *(sic)*	Please refer to the first paragraph above.
3.	10/21/2011 William Vanaskie, Executive VP/COO Maricopa Integrated Health System	The AHCCCS program has approached the 340B Community Health Centers (CHC) providing services to Medicaid eligible outpatients with the plan to change the reimbursement model to one tied to the entity's drug acquisition plus cost of dispensing (COD) designed to "cover" the organization's cost while removing any positive revenue stream. This proposed AHCCS ruling is being done in conjunction with an effort to have Arizona participate in the federal rebate program and associated efforts to contain AHCCCS programmatic costs. This change appears inconsistent with the original tenants of the 340B statutes and will effectively penalize those entities, especially qualified Community Health Centers, by not only eliminating a positive revenue source but in almost all cases turning this service into a revenue losing proposition. The consequences of this move are obvious. In order to continue to serve the medical needs of the Medicaid population, CHC's will need to cut prescription services in total or not secure the drugs under the 340B program and attempt to negotiate low acquisition costs that could then be covered by existing reimbursement rates. In either case the results will mean less rebates available to AHCCCS.	The state is permitted to collect rebates for prescription drugs dispensed to Medicaid eligible persons by a CHC if the drugs were not purchased through the 340B program. The Medicaid Act already requires full cost reimbursement for FQHCs and RHCs services, as defined in federal law, which are provided to AHCCCS members. Those services do not include pharmacy services. With respect to pharmacy services, the Medicaid Act requires that states establish reimbursement rates that are consistent with efficiency, economy, quality of care, and access to care. AHCCCS believes that the reimbursement methodology described in this rule meets that standard. Federal courts have interpreted this requirement to mean that payment rates for pharmacy services must be reasonably related to the cost of the services. However, it does not require Medicaid agencies to cover the actual cost of pharmacy services provided in FQHCs, and FQHC Look-Alikes and 340B entity contracted pharmacies.

Numb:	Date/ Commentor:	Comment:	Response:
3. *continued*		We believe this rule is short-sighted and will not result in the quantity of rebates the AHCCCS Program anticipates. Therefore, the change will be pointless. There are other alternatives that should be pursued if AHCCCS persists in reducing the cost of providing services to the Medicaid population.	AHCCCS is mandated to participate in the federal rebate program. The intent of the 340B statutes was not to encourage entities to reap excessive profits from the Medicaid Program. AHCCCS does not expect to receive increased rebates since the proposed rule requires the entity to submit the actual acquisition cost for drugs subject to the 340B pricing file so that the savings will now be passed on to the state on the front end. The state will not be able to submit the utilization for these drugs for purposes of obtaining Medicaid rebates since AHCCCS will have obtained the discount on the front end.
4.	10/21/2011 Michael F. Smith, Senior Manager Karl Meehan, VP, Walgreens	AHCCCS' proposed rule, as written, poses unworkable requirements on contract pharmacies. If left unmodified, the proposed rule could harm high-risk patient population, while providing little, if any, financial benefit to AHCCCS. The following concerns and considerations should be accounted for before a decision is made to proceed with the implementation of the proposed rule: 1. The proposed rule refers in several sections to 'claims for drugs purchased under the 340B pricing program. The references imply the utilization of a prospective model whereby covered entities and their contract pharmacies dispense inventory already purchased at 340B pricing, and subsequently submit claims for these drugs. Walgreens uses a replenishment (retrospective) model for 340B claims, which is the prevalent industry model. Such model is operationally more efficient as well as more effective in preventing drug diversion and avoiding duplicate discounts. Pharmacy industry participants, including several State Medicaid agencies are using the National Council of Prescription Drug Programs (NCPDP) forum to develop a solution (described later in the proposed solution section of this letter) that is in line with the more commonly-used replenishment model. The proposed rule is at odds with the replenishment model, and creates a situation where entities and contract pharmacies that use this model are unable to meet the requirements set forth.	On March 15, 2000, the Department of Health and Human Services, Health Resources and Services Administration, issued a Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification (Duplicate Discounts). "For appropriate Medicaid drug reimbursement procedures, the Health Resources and Services Administration (HRSA) refer the covered entity to its respective State Medicaid agency for guidance." AHCCCS is the state agency responsible for administering the Medicaid program for the state of Arizona. The proposed rule defines the 340B claims submission procedures for FQHC and FQHC Look-Alike pharmacies. (Note that the application of this methodology to 340B contracted pharmacies has been removed in the supplemental rulemaking). A covered entity may have a replenishment model or other contractual arrangement between the 340B entity and their contracted pharmacies; however, this should not be confused with pharmacies that are contracted with the AHCCCS FFS PBM or the AHCCCS Contractors' PBMs. The first is how the pharmacy procures the drug and the latter is how payment is issued for the drug when it is dispensed to an AHCCCS member. Irrespective of any arrangement that FQHC's and FQHC Look-Alikes have with a contracted pharmacy, the FQHC or FQHC Look-Alike must submit claims for drugs eligible for 340B pricing to the AHCCCS FFS PBM and/or AHCCCS Managed Care Contractors' PBMs with the lesser of the actual acquisition cost of the drug or the 340B ceiling price. This is a similar model to that of other states. The submission of this amount also creates a fully transparent model whereas the replenishment model does not provide transparency.

Numb:	Date/ Commentor:	Comment:	Response:
4. *continued*		2. Section 7 of the preamble requires the agency to provide references to any study relevant to the rule that the agency reviewed and proposes to rely on its evaluation or justification of the rule where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material. In this section, the agency has responded by stating, "The Administration has analyzed the data through the study and AHCCCS claims data at the NDC level for the 1st quarter of 2011; the results of this analysis demonstrated a net savings valued at approximately $7.1M annually". The methodology behind the above-mentioned data analysis exercise has not been clearly described in this or other sections of the preamble. Section 9 mentions that the 'The AHCCCS Administration believes that the cost differential, when comparing 340B pricing to the PBM reimbursement rate paid to the 340B entity and its contracted pharmacy, can be saved and benefit the state'. As you are aware, 340B claims may not be submitted to manufacturers by Medicaid programs for rebates because the manufacturer has already extended a discount to the covered entity when the drug was initially purchased. It is unclear whether AHCCCS' analysis accounted for the loss of revenue to the state from not collecting rebates as a result reimbursing the pharmacy using 340B drug pricing. Until this loss of revenue from rebates is factored in, the estimated $7.1 million figure quoted is potentially overstated. It is vital that the data and methodology employed in the analysis, and any supporting material be transparently available to all stakeholders.	AHCCCS calculated a potential savings of $7.1M for its expenditure for prescription drugs under the proposed reimbursement methodology based on prescriptions that were purchased through the 340B Pricing Program by FQHC's and FQHC Look-Alikes. The analysis did not include prescriptions filled and dispensed to AHCCCS members by 340B entity contracted pharmacies. AHCCCS is not permitted to submit claims, for drugs purchased under the 340B Pricing Program, to manufacturers and subsequently collect rebates from them under the federal rebate program as this would be considered obtaining "duplicate discounts" (one for the 340B entity and the second for the state Medicaid agency). The proposed rule, revised through supplemental rulemaking, requires that FQHC and FQHC Look-Alike pharmacies identify all drugs dispensed which are eligible for 340B pricing upon submission to the AHCCCS FFS PBM and/ or the AHCCCS Managed Care Contractors' PBMs to ensure that duplicate discounts are prevented.
		3. Section 7 relies on the "Cost of Dispensing Study" as the basis for setting the $8.75 dispense fee to entities and contract pharmacies. It is important to note however that the Grant Thornton study concluded that the median cost to fill a prescription is $10.50 in 2007, nearly five years ago. AHCCCS indicated it used an adjustment factor based on geographic practice cost indices to determine the Arizona cost of dispensing.	The Grant Thornton study is one among several information sources viewed by AHCCCS. Section 7 of the preamble has been revised to clarify this. The COD cited by the commenter is identified in that study as the "average per prescription." AHCCCS believes that, given the likelihood of outliers in the type of data studied, median is the better measure of central tendency.

Numb:	Date/ Commentor:	Comment:	Response:
4. *continued*		However, Section 7 does not provide the analysis or other supporting data related to that adjustment factor for the public to review. In the event that AHCCCS decides to elect to proceed with implementation of the proposed rule despite the concerns expressed, there are serious risks that contract pharmacies will be reimbursed by AHCCCS below the pharmacies' true costs, creating further negative impacts to the pharmacies and the 340B program. One such impact may be the reduction in 340B contract pharmacies in Arizona thus limiting the availability of pharmacy care which the 340B program was intended to promote and broaden. Alternatively, contract pharmacies would look to the covered entity to make up for the short fall in reimbursement received from AHCCCS. If a contract pharmacy agreed to accept reimbursement rates below its cost on behalf of the covered entity, such arrangement could implicate the Federal Anti-Kickback Statue which prohibits one entity from providing another entity any remuneration in exchange for referrals of patients. Consequently, the reimbursement amounts that covered entities would have to pay contract pharmacies to make up for the shortfall in AHCCCS payments would reduce the resources available to that covered entity to provide greater access to healthcare as intended by the 340B program. 4. Pharmacy industry participants, including other State Medicaid Agencies, are using the NCPDP forum to develop a solution where Medicaid agencies will be able to meet the requirements to participate in the Federal Medicaid Drug Rebate Program, and comply with regulations prohibiting duplicate discounts. The approach outlined in the proposed rule is at odds with the solution being developed at NCPDP with broader stakeholder representation and input. This solution is expected to be ready for implementation during 2012 and is described in the 'Potential Solutions' section below.	In viewing the Grant Thornton study, as well as other studies presenting similar information, AHCCCS gave its attention to the median COD per prescription. The AHCCCS FFS PBM and AHCCCS Managed Care Contractors' PBMs provide statewide networks and access to care that meet Medicaid standards. The contracts between 340B entities and their contract pharmacies do not affect these statewide networks and members can obtain pharmaceutical services from an extensive network of pharmacies throughout the state. AHCCCS has not identified any implications with the Federal Anti-Kickback Statute and suggest you confer with your legal counsel.

Numb:	Date/ Commentor:	Comment:	Response:
4. *continued*		**Potential Solutions:** There are two mutually exclusive solutions available to allow State Medicaid agencies with the regulation to participate in the Federal Medicaid Drug Rebate Program, while preventing duplicate discounts as required under federal regulations for the 340B program. 1. Similar to the current practice of carving-out FFS Medicaid programs, covered entities and contract pharmacies are able to carve-out Medicaid MCO claims from the 340B-qualified claims set. Under this arrangement, Medicaid programs can safely collect rebates from manufacturers without risk of duplicate discounts, since the pharmacy's non-340B acquisition costs are always used to submit and reimburse claims. 2. Under the next HIPAA-approved version of the NCPDP Standard (Version D.0), solutions are being developed to eliminate risk of duplicate discounts that address both the prospective and the replenishment models in use in the 340B industry today. The timeline for implementation of these solutions is during 2012. a. **Prospective Model Solution:** If a pharmacy knows at the time of claim submission that product obtained at 340B drug pricing will be dispensed, an identifier on the outbound claim will be set on the claim to identify it as 340B. The ingredient cost field is also modifiable to submit the 340B acquisition cost. b. **Replenishment Model Solution:** Pharmacies will be able to retrospectively identify to the PBM/processor any claims where they received inventory replenishment at 340B pricing. The PBM/processor will exclude these prescriptions from the rebate processing with manufacturers.	AHCCCS will amend the proposed rule to specify that AHCCCS shall not reimburse 340B Contracted Pharmacies for 340B purchased drugs. However, contracted pharmacies that are in the AHCCCS FFS and Managed Care Contractors Pharmacy Networks may continue to submit claims to the AHCCCS FFS and Managed Care Contractors' PBMs for reimbursement of drugs that are not purchased through the 340B Pricing Program…. Reimbursement to contracted pharmacies is limited to contracted pharmacies in the AHCCCS or Managed Care Contractor network for drugs not purchased under the 340B program. AHCCCS and Managed Care Contractors shall reimburse these drugs at the price and dispensing fee set forth in the contract. Per the proposed rule, AHCCCS will communicate prescription claims submission requirements, including, but not limited to, the NCPDP claims submission fields for the "340B Claim Identifier" and the Actual Acquisition Cost/340B Ceiling Price to the AHCCCS FFS PBM and to AHCCCS Managed Care Contractors.

Numb:	Date/ Commentor:	Comment:	Response:
5.	10/21/2011 Maureen Testoni, Assistant General Council, Safety Net Hospitals for Pharmaceutical Access	The proposed rule would require certain covered entities to bill AHCCCS and its contractors at the 340B ceiling price plus a dispensing fee of $8.75. As discussed below, the undersigned organizations, which represent safety net providers that participate in the 340B program, have grave concerns about such a policy and believe that it is contrary to federal law. We recommend that AHCCCS instead consider a reimbursement policy that may have greater savings potential wherein AHCCCS and covered entities share the savings generated when drugs are purchased with the 340B discount. **A. The Proposed Rule Conflicts with the Federal Exemption of 340B Drugs from Managed Care Rebates** The preamble to the proposed rule states that AHCCCS is imposing this rule as a result of the Patient Protection and Affordable Care Act (PPACA), which required all state Medicaid programs, including AHCCCS, to participate in the federal drug rebate program. The preamble further states that 340B drugs are not eligible for rebates and that this prohibition is intended to protect manufacturers from paying two discounts on a drug – the 340B discount and the Medicaid rebate. Finally, the preamble explains that it is imposing this lower reimbursement rate in order to address the disparity between the actual acquisition cost of drugs subject to 340B pricing and the current reimbursement rate received from pharmacy benefit managers (PBMs). Prior to PPACA, drugs furnished by Medicaid managed care plans were exempt from rebate requirements. PPACA extended Medicaid fee-for-service drug rebate requirements to Medicaid managed care. By imposing an obligation on states to collect rebates, PPACA created a new revenue stream for states. Importantly, 340B drugs were specifically exempted from this requirement and the new revenue stream for states. The purpose of this exemption was not to protect managed care organizations from duplicate discounts, as there is already language in the 340B statute prohibiting covered entities from requesting payment under Medicaid for 340B drugs. Rather, the intent was to protect 340B covered entities and the vulnerable patients they serve by exempting the 340B program from the new revenue stream created for the states. In this way, Congress preserved the existing status quo.	The provisions of sections 340B of the Public Health Service Act and Section 1927 of the Social Security Act regarding duplicate payments were not intended to protect 340B covered entities such as FQHC's and FQHC Look-Alikes. These laws were enacted to protect drug manufacturers from having to provide BOTH a discount to a 340B entity and a rebate to the State Medicaid agency for the same drug. Neither section 340B of the Public Health Service Act nor the Medicaid Act restricts the State Medicaid agency for establishing the reimbursement method established in this rule; in fact, HRSA directs entities to their respective state for guidance.

Numb:	Date/ Commentor:	Comment:	Response:
5. *continued*		States were not receiving revenue from 340B managed care drugs prior to PPACA, and the exemption ensured that they would not receive any such revenue as a result of PPACA. AHCCCS's proposal to mandate-billing to managed care organizations at the 340B ceiling price conflicts with the federal exemption for 340B from the Medicaid managed care rebate requirements, and is therefore pre-empted by PPACA. This federal protection is consistent with Congressional intent with regard to the 340B program. Congress created the 340B program to enable safety-net providers to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services." This purpose cannot be achieved if 340B covered entities have to pass on all of the savings they receive from third parties. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give providers when it established the 340B program. As discussed in a recent report by the Government Accountability Office (GAO), 340B providers are using the additional revenue they receive to further the program's purpose, such as by maintaining services and lowering medication costs for patients. The GAO also reported that many covered entities do not generate enough revenue from the 340B program to offset drug related costs. AHCCCS's proposal undermines the very nature of the 340B program and will result in fewer services and other assistance for vulnerable patient populations. **B. The Proposed Rule Interferes with Federal Requirements Governing Medicaid Managed Care Plans** Imposing fee schedules that managed care organizations must follow may impermissibly interfere with federal statutory requirements. The provisions in the Medicaid statute that govern use of managed care arrangements specifically state that payment to managed care entities is to be made on a prepaid capitation basis. The statute is clear that this involves the allocation of risk. Under this model, states pay a prospective amount per recipient to the managed care organization in return for the organization providing all covered services to Medicaid recipients. In order for the managed care organization to furnish the care within the	The Managed Care provisions of the Medicaid Act do not prohibit the State Medicaid agency from establishing reimbursement methodologies for particular items or services that are binding on MCOs. Capitation rates take this methodology into consideration.

Numb:	Date/ Commentor:	Comment:	Response:
5. *continued*		payment amount received, the organization must *manage* the recipients' care, which involves negotiating payment rates with providers, utilization review, etc. By imposing reimbursement requirements on managed care companies, AHCCCS is interfering with the allocation of risk and the organization's obligation to manage enrollees' care, which conflicts with the federal requirements cited above.	
		C. The Proposed Rule Violates Federal Confidentiality Requirements, HRSA Guidance, and Requests Information that 340B Entities Currently Do Not Possess The proposed rule also contains a provision that requires 340B entities to "provide the 340B pricing file to the AHCCCS Administration upon request." This requirement violates federal confidentiality requirements, guidance issued by the Health Resources and Services Administration ("HRSA"), and copyright laws. Moreover, covered entities do not have access to any ceiling prices that they can be assured are accurate and are prohibited from sharing estimated ceiling prices they receive from wholesalers. The 340B ceiling price is defined in Section 340B of the Public Health Services statute as "the maximum price that covered entities may permissibly be required to pay" for a 340B drug. The ceiling price is calculated based on a drug's average manufacturer price and "best price," both of which are defined in section 1927 of the Social Security Act. The Medicaid statute, the 340B pharmaceutical pricing agreement ("PPA"), and HRSA guidance all provide, with some variation, that the information disclosed by the manufacturer is confidential and prohibits disclosure of this information. The Medicaid drug rebate statute, at Section 1927(b)(3)(D) of the Social Security Act, specifies that drug pricing information "shall not be disclosed by the [Government] … in a form which discloses the identity of a specific manufacturer or wholesaler, [or] the prices charged for drugs" except as necessary to carry out the provisions of the Act or for certain other limited purposes, including the Medicaid rebate	Neither Section 340B of the Public Health Service Act nor Section 1927 of the Social Security Act prohibits an FQHC, FQHC Look-Alike, or their contracted pharmacies from providing this information to a State Medicaid agency.

Numb:	Date/ Commentor:	Comment:	Response:
5. *continued*		program. HRSA has taken the position that 340B ceiling prices could be considered this type of "form" that would reveal manufacturers' prices. In line with this reasoning, HRSA has interpreted this provision to mean that covered entities may not disclose 340B ceiling prices. Pharmaceutical manufacturers rely on this guidance and are quick to take action when they believe their calculated 340B ceiling prices have been improperly disclosed. We are aware that, pursuant to PPACA, the Department of Health and Human Services (HHS) is required to make 340B ceiling prices available to covered entities on a password-protected website. Nothing in PPACA, however, authorizes a covered entity to disclose its 340B prices to a payer. Likewise, there is nothing in the Medicaid statute, PPA, or HRSA guidance that establishes an exception to 340B confidentiality standards when a covered entity bills its 340B drugs. Therefore, mandating disclosure of ceiling prices violates federal law. In addition, covered entities currently do not have access to this information. The pricing information from manufacturers that is necessary to calculate the ceiling price is not publicly available. It is for this reason that PPACA included language requiring that HHS make ceiling prices available to covered entities, as there is currently no way for them to determine whether they are being charged the correct 340B ceiling price. Covered entities must rely on 340B price lists that are published by wholesalers, though there is no way for them to evaluate whether the price on the list truly represents the 340B ceiling price. Such lists, however, are not available to the public and wholesalers and manufacturers have not authorized covered entities to disclose this information. Manufacturers consider such information to be proprietary and object to the sharing of such information. **D. AHCCCS Should Evaluate the Potential Savings to be Gained by Sharing a Higher Percentage of the 340B Discount with Covered Entities** The proposed rule sets a dispensing fee for 340B drugs of $8.75. We have been told that this rate is well below the cost of dispensing for the vast majority of covered entities affected by the proposed rule. As mentioned above, the GAO recently found that covered entities use the savings from the 340B	See above response for item 5(A).

Numb:	Date/ Commentor:	Comment:	Response:
5. *continued*		discount to maintain services and lower medication costs for patients, though for many, savings from the 340B program is insufficient to cover drug related costs. Lowering reimbursement to cost and establishing a below-cost dispensing fee could have a catastrophic impact on these covered entities and their patients. It is also likely to lead to less savings for AHCCCS than could be achieved with a dispensing fee that was closer to covered entities' true costs. The Office of the Inspector General (OIG) recently issued a report evaluating State Medicaid polices related to the 340B-purchased drugs. The OIG concluded that many states misunderstand federal policy regarding 340B billing and that states could save money through shared savings arrangements with covered entities even if the state paid such entities higher dispensing fees. By requiring covered entities to bill their actual acquisition cost (AAC), Medicaid agencies are leading nearly 60 percent of covered entities to carve-out their Medicaid drugs from 340B purchases. When a covered entity carves-out, it does not have access to the 340B discount and Medicaid pays its standard reimbursement rate for the drugs and the state receives only the Medicaid rebate as its discount. Typically, the 340B price is significantly lower than the standard Medicaid rate after rebate, therefore, as a result of the AAC billing policies, States are foregoing higher discounts on drugs then they currently receive through the rebate program. Covered entities carve-out in these situations because the dispensing fee associated with the AAC payment rate is much lower than the covered entities' actual cost to dispense the drug, resulting in a significant loss when dispensing 340B drugs. Recognizing the potential for higher drug savings, some states have developed reimbursement policies that set payment levels to encourage covered entities to use 340B drugs for their Medicaid patients. In this way, states and providers share the spread between the 340B discount and the standard Medicaid reimbursement rate. These "shared savings" policies result in a win-win for both state Medicaid programs and covered entities.	

Numb:	Date/ Commentor:	Comment:	Response:
5. *continued*		For example, Massachusetts took steps in 2007 to increase its payment for 340B drugs with the goal of encouraging covered entities to carve-in to Medicaid. By offering an enhanced dispensing fee for 340B retail drugs of $10.00, Massachusetts Medicaid dramatically increased the number of providers carving in their 340B drugs. When Massachusetts began looking into this issue in 2002, only three covered entities carved-in to Medicaid. By 2010, the carve-in rate for DSH was over 75%, representing 68 registered sites. As a result, Massachusetts netted $6.5 million in additional revenue in 2010 alone. Importantly, Massachusetts used its shared savings arrangement to improve access to lifesaving medications for the state's low-income population. AHCCCS has the opportunity to establish a win-win situation with 340B entities in Arizona. Failure to do so is likely to result in some covered entities having to close their doors and other covered entities opting to carve-out their 340B drugs from Medicaid. Both situations result in lower savings for AHCCCS and potentially irreversible harm to the patients served by these covered entities. We strongly encourage AHCCCS to revisit the amount of the dispensing fee and to set the rate at a level that more closely reflects the true dispensing costs of the covered entities affected by this proposed rule.	
6.	John Pacey Regional Pharmacy Director, United Health Care and State APIPA	By the time the proposed rule is finalized in November, the Medicaid contractors will have less than 60 days to work with their Pharmacy Benefit Managers (PBM's) to plan, build, and test the claims processing functionality of this new benefit. Also, new contract addendums with the FQHC network also need to be distributed, signed and returned by the FQHC pharmacies.	

Numb:	Date/ Commentor:	Comment:	Response:
6. *continued*		PBM's are extremely busy in the October, November, December quarter, building and testing all new benefits effective 1/1/12. This short time frame would place an unnecessary burden not only on the PBM, but on the contractors' pharmacy departments as well. This 340-B benefit is an entirely new program that will require AHCCCS supplied pricing files, FQHC pharmacy information, and a written process on exactly how the program will operate, process claims, and submit encounter data to AHCCCS correctly the first time. Any processing or pricing glitches in the beginning could doom this project from the start with the FQHC pharmacy network. There are many moving parts, and different scenarios, that will require at least 90 days to build, test, implement and notify providers in advance of this major process change in contractor pharmacy programs. With the above, I ask that AHCCCS reconsider the start date of this program and allow at least 90-120 days lead time for all contractors to plan, build and implement the 340-B pharmacy program to ensure it begins operating correctly from day one, without any issues caused by contractors rushing to complete the implementation by the proposed starting date.	AHCCCS recognizes that contractors and subcontractors may require a minimum of 30 days to facilitate and implement the rule requirements and will ensure timely notification is provided.
7.	John Swagert, CEO Mountain Park HC	We believe the proposed changes in AHCCCS reimbursement to 340B FQHC pharmacies will do more harm than good. By providing a dispensing fee that is below the actual cost of dispensing medication, AHCCCS will be forcing pharmacies like ours to shift pharmacy costs to uninsured patients in order to maintain financially viable Pharmacy services. It is of course true that AHCCCS is not responsible for the cost of care for the uninsured. But we know that our uninsured patients cycle on and off AHCCCS, just as they cycle on and off commercial insurance—as their individual economic circumstances change, as jobs are gained or lost, or as employers stop offering coverage. Uninsured patients with chronic conditions requiring long-term medications who can't afford to fill their prescriptions will be sicker, and costlier to take care of, should economic circumstances land them on the AHCCCS roles.	See above response for item 1.

Numb:	Date/ Commentor:	Comment:	Response:
7. *continued*		We join the Arizona Association of Community Health Centers in asking that AHCCCS reconsider the proposed dispensing fee of $8.75. We further ask that AHCCCS use the data from The Grant Thornton National Cost of Dispensing (COD) Study Final Report January 26, 2007, cited by AHCCCS as a credible source, as the basis of a dispensing fee that could be expected to cover the actual cost. That study found a cost of over $12 in 2006, which would be between $14 and $15 after adjustment for inflation.	
8.	10/22/2011 Mary Brubaker, Director of Pharmacy, North Country HC	Our primary concerns are loss of revenue for both the in-house pharmacy and our contracted pharmacies, deterioration in patient outcomes, and possible elimination of services within our clinics. The proposed reimbursement model of 340b acquisition cost plus $8.75 dispensing fee will result in a 26% decrease in revenue from the AHCCCS managed care plans. In order to maintain the same amount of revenue paid by AHCCCS to North Country in 2010, the dispensing fee needs to be in the range of $15.50 to $16.00 per prescription. At the initial meeting with the medical and pharmacy director of AHCCCS, they stated it was their intent to make sure the CHC pharmacies remained "whole". Within the North Country service area are several clinics in communities without retail pharmacy services. Currently the North Country pharmacy provides through a variety of options, medication deliveries to the local clinic for distribution to those patients. With the change in reimbursement, these patients may need to find other means for securing their medications or simply go without. Medication adherence remains a major player in the overall healthcare costs to our state. Many factors are involved in why patients do not take their medications. Since cost is generally not one of the factors with AHCCCS coverage, consideration needs to be given to the patient's understanding of the value of the medications in their care, adverse reactions, and simply transportation barriers. The focus of community health center pharmacies is to provide care for uninsured and underserved, and to minimize health care disparities. The loss in revenue will likely affect our services to the patients most at risk. (Lars Osterberg, M.D., and Terrence Blaschke, M.D. N Engl J Med 2005; 353:487-497; Adherence to Long-Term Therapies, Evidence for Action, WHO 2003.)	See above response for item 1.

Numb:	Date/ Commentor:	Comment:	Response:
8. *continued*		If the pharmacy is not able to at least break even on AHCCCS prescriptions, then the center will need to reevaluate all services provided by the clinic. While the proposed change in the reimbursement model may be a short term fix, the down stream effect will likely be an increase in patient medical costs. The utilization of the emergency room increases, absenteeism increases and productivity decreases. The question to be answered is if the increase in pharmaceutical rebates will offset the increase in medical care costs. (Asheville Project, Barry A. Bunting, Benjamin H. Smith, and Susan E. Sutherland *J Am Pharm Assoc.* 2008; 48:23–31). We encourage AHCCCS to reconsider their proposed reimbursement model, and either return to the current contract pricing, or to increase the dispensing fee to more closely reflect the pharmacy's cost. It is the intent of all of us to provide the best care for these vulnerable patients.	
9.	10/23/2011 Kathy Byrne, CEO El Rio Comm HC	The El Rio Community Health Center wishes to highlight our concerns with the proposed regulations relating to the 340b program and its impact on organizations like our own. While we were heartened by the early discussion with representatives of AHCCCS regarding supplementing the acquisition cost payment methodology with an enhanced dispensing fee the fee proposed of $8.75 falls short of our cost of operating pharmacy services. The introduction to the proposed regulations draw attention to the Grant Thornton National Cost Study which is based on 2006 costs and shows an average dispensing cost of $12.31 for Medicaid. If this analysis was framed in current dollars using the physician CPI the cost of dispensing would be $14.82. Given the study that AHCCCS highlighted we are at a loss to understand why the fee of $8.75 was chosen. For the El Rio Community Health Center the implementation of this change in our method of reimbursement means a loss of over $4.00 per prescription- a loss of over $700,000 based on our current volume. We are even more concerned with the very recent news that Walgreens will no longer participate in the pharmacy network of some of the health plans serving Pima County. It is likely we will see growth in the number of our AHCCCS patients using our pharmacies and ever more significant losses.	See above response for item 1.

Numb:	Date/ Commentor:	Comment:	Response:
9. *continued*		We would encourage AHCCCS to look more fully at the impact of the proposed rule and the possible unintended consequences associated with the proposed change including health centers having to reduce access to pharmacy services. We believe that rather than restricting access to 340b program benefits the State should be encouraging greater use of this great program. We would also like to support the analysis that has been presented and submitted by the Arizona Association of Community Health Centers.	

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision:

Not applicable

9. The preliminary summary of the economic, small business, and consumer impact:

For purposes of the proposed rule "340B entities" is limited to FQHC and FQHC Look-Alike pharmacies.

The AHCCCS Administration believes that the cost differential, when comparing 340B pricing to the PBM reimbursement rate currently paid to the FQHC and FQHC Look-Alike pharmacies, can be saved and benefit the state.

The proposed rule requires 340B entities, FQHC and FQHC Look-Alike pharmacies to submit claims for drugs identified in the 340B pricing file using the lesser of the 340B entity's actual acquisition cost and the 340B ceiling price. The 340B covered entity must submit claims with the lower of the two amounts irrespective of whether or not the 340B covered entity purchases the drug under the 340B pricing program. The AHCCCS Administration and its Contractors shall reimburse the 340B covered entity at the lower amount plus a 340B specific dispensing fee. Beginning February 1, 2012, the dispensing fee established for reimbursement of 340B purchased drugs will be $8.75. The dispensing fee will be available on the capped fee schedule for the public at: www.azahcccs.gov.

This methodology substantially reduces the higher payments AHCCCS and its Managed Care Contractors currently provide to FQHC and FQHC Look-Alike pharmacies for drugs which are available to 340B covered entities at discounted rates. The estimated net cost savings resulting from reimbursing the covered entities at the lower of the 340B actual acquisition cost or the 340B ceiling price, plus the dispensing fee of $8.75, is $7.1M. It should be noted that these approximate savings and dispensing fee costs do not take into consideration the prescriptions filled at 340B contracted pharmacies which are not subject to this methodology.

With respect to drugs dispensed by FQHC and FQHC Look-Alike pharmacies that are not eligible for purchase under the 340B pricing program, the AHCCCS Administration and its Managed Care Contractors shall reimburse covered entities for these drugs at the price and dispensing fee specified in contract or at the AHCCCS Fee-for-Service schedule, whichever is applicable.

The proposed rule also delineates reimbursement to pharmacies that contract with 340B covered entities to dispense drugs as part of the 340B program. The rule prohibits AHCCCS and its Managed Care Contractors from reimbursing 340B contracted pharmacies for 340B purchased drugs. AHCCCS authorizes reimbursement to 340B Contracted Pharmacies that are contracted with AHCCCS and its Managed Care Contractors' PBMs, for drugs not purchased under the 340B Drug Pricing Program. Reimbursement for such drugs will be at the price and dispensing fee set forth in their respective PBM contracts with AHCCCS and its Managed Care Contractors.

10. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name: Mariaelena Ugarte

Address: AHCCCS
Office of Administrative and Legal Services
701 E. Jefferson St., Mail Drop 6200
Phoenix, AZ 85034

Telephone: (602) 417-4693

Fax: (602) 253-9115

E-mail: AHCCCSrules@azahcccs.gov

Web site: www.azahcccs.gov

11. The time, place, and nature of the proceedings to make, amend, renumber or repeal the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the supplemental proposed rule:
Close of the comment period is: January 2, 2011, 5:00 p.m. A person may submit their comments or request an oral proceeding via mail, fax or e-mail to the contact information listed under item 4.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:
None

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:
Not applicable

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:
Not applicable

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
Not applicable

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:
None

14. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

ARTICLE 7. STANDARDS FOR PAYMENTS

Section
R9-22-710. Payments for Non-hospital Services

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-22-710. Payments for Non-hospital Services

A. Capped fee-for-service. The Administration shall provide notice of changes in methods and standards for setting payment rates for services in accordance with 42 CFR 447.205, December 19, 1983, incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC~~,~~ 20401. This incorporation by reference contains no future editions or amendments.

1. Non-contracted services. In the absence of a contract that specifies otherwise, a contractor shall reimburse a provider or noncontracting provider for non-hospital services according to the Administration's capped-fee-for-service schedule.
2. Procedure codes. The Administration shall maintain a current copy of the National Standard Code Sets mandated under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004), incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC~~,~~ 20401. This incorporation by reference contains no future editions or amendments.
   a. A person shall submit an electronic claim consistent with 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
   b. A person shall submit a paper claim using the National Standard Code Sets as described under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
   c. The Administration may deny a claim for failure to comply with subsection (A)(2)(a) or (b).
3. Fee schedule. The Administration shall pay providers, including noncontracting providers, at the lesser of billed charges or the capped fee-for-service rates specified in subsections (A)(3)(a) through ~~(A)(3)(d)~~ (d) unless a different fee is specified in a contract between the Administration and the provider, or is otherwise required by law.
   a. Physician services. Fee schedules for payment for physician services are on file at the central office of the Administration for reference use during customary business hours.
   b. Dental services. Fee schedules for payment for dental services are on file at the central office of the Administra-

tion for reference use during customary business hours.

c. Transportation services. Fee schedules for payment for transportation services are on file at the central office of the Administration for reference use during customary business hours.

d. Medical supplies and durable medical equipment (DME). Fee schedules for payment for medical supplies and DME are on file at the central office of the Administration for reference use during customary business hours. The Administration shall reimburse a provider once for purchase of DME during any two-year period, unless the Administration determines that DME replacement within that period is medically necessary for the member. Unless prior authorized by the Administration, no more than one repair and adjustment of DME shall be reimbursed during any two-year period.

B. Pharmacy services. The Administration shall not reimburse pharmacy services unless the services are provided by a ~~contracted provider or a provider~~ pharmacy having a subcontract with a Pharmacy Benefit Manager (PBM) contracted with AHCCCS. Except as specified in subsection (C), the ~~The~~ Administration shall reimburse pharmacy services according to the terms of the contract.

C. FQHC Pharmacy reimbursement.

1. For purposes of this Section the following terms are defined:
   a. "340B Drug Pricing Program" means the discount drug purchasing program described in 42 U.S.C. 256b.
   b. "340B Ceiling Price" means the maximum price that drug manufacturers can charge covered entities participating in the 340B Drug Pricing Program as reported by the drug manufacturer to HRSA.
   c. "340B entity" means a covered entity, eligible to participate in the 340B Drug Pricing Program, as defined by the Health Resources and Human Services Administration.
   d. "Actual Acquisition Cost (AAC)" means the purchase price of a drug paid by a pharmacy net of discounts, rebates, chargebacks and other adjustments to the price of the drug. The AAC excludes dispensing fees.
   e. "Contracted Pharmacy" means an arrangement through which a 340B entity may contract with an outside pharmacy to provide comprehensive pharmacy services utilizing medications subject to 340B pricing.
   f. "Dispensing Fee" means the amount paid for the professional services provided by the pharmacist for dispensing a prescription. The Dispensing Fee does not include any payment for the drugs being dispensed.
   g. "Federally Qualified Health Center" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the criteria under sections 1861(aa)(4) and 1905(l)(2)(B) of the Social Security Act and receives funds under section 330 of the Public Health Service Act.
   h. "Federally Qualified Health Center Look-Alike" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the definition of "health center" under section 330 of the Public Health Service Act, but does not receive grant funding under section 330.
2. Effective the later of February 1, 2012, or CMS approval of a State Plan Amendment, an FQHC or FQHC Look-Alike shall:
   a. Notify the AHCCCS provider registration unit of its status as a 340B covered entity no later than:
      i. 30 days after the effective date of this Section;
      ii. 30 days after registration with the Health Resources and Services Administration (HRSA) for participation in the 340B program; or
      iii. The time of application to become an AHCCCS provider.
   b. Provide the 340B pricing file to the AHCCCS Administration upon request. The 340B pricing file shall be provided in the file format as defined by AHCCCS.
   c. Identify 340B drug claims submitted to the AHCCCS FFS PBM or the Managed Care Contractors' PBMs for reimbursement. The 340B drug claim identification and claims processing for a drug claim submission shall be consistent with claim instructions issued and required by AHCCCS to identify such claims.
3. The FQHC and the FQHC Look-Alike pharmacies shall submit claims for AHCCCS members for drugs that are identified in the 340B pricing file, whether or not purchased under the 340B pricing file, with the lesser of:
   a. The actual acquisition cost, or
   b. The 340B ceiling price.
4. The AHCCCS Fee-for-Service and Managed Care Contractors' PBMs shall reimburse claims for drugs which are identified in the 340B pricing file dispensed by FQHC and FQHC Look -Alike pharmacies, whether or not purchased under the 340B pricing file, at the amount submitted under subsection (C)(3) plus a dispensing fee listed in the AHCCCS Capped Fee-For-Service Schedule unless a contract between the 340B entity and a Managed Care Contractor's PBM specifies a different dispensing fee.
5. The AHCCCS Administration and Managed Care Contractors shall not reimburse contracted pharmacies for drugs dispensed under an agreement with the 340B entity as part of the 340B drug pricing program.
6. The AHCCCS Administration and Managed Care Contractors shall reimburse contracted pharmacies for drugs not dispensed under an agreement with the 340B entity as part of the 340B program at the price and dispensing fee set forth in the contract between the contracted pharmacy and the AHCCCS or its Managed Care Contractors' PBMs. Neither the Administration nor its Managed Care Contractors will reimburse a contracted pharmacy that does not

have a contract with the Administration or MCO's PBM.

7. The AHCCCS Administration and its Managed Care Contractors shall reimburse FQHC and FCHC Look-Alike pharmacies for drugs that are not eligible under the 340B Drug Pricing Program at the price and dispensing fee set forth in their contract with the AHCCCS or its Managed Care Contractors' PBMs.
8. AHCCCS may periodically conduct audits to ensure compliance with this Section.

NOTICE OF EXEMPT RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE AGRICULTURAL COUNCILS AND COMMISSIONS

Editor's Note: The following Notice of Exempt Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2577.)

[R11-196]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

Article 6	Amend
R3-9-601	Amend
R3-9-602	Amend
R3-9-603	Amend
R3-9-604	Amend
R3-9-605	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific), and the statute or session law authorizing the exemption:

Authorizing statute: A.R.S. § 3-414(C)(11)

Implementing statute: A.R.S. § 3-404(B)(2), (8)

Exemption: A.R.S. §§ 3-414(C)(11) and 41-1005(A)(29)

3. The effective date of the rule and the agency's reason it selected the effective date:

November 29, 2011. The effective date is the date the Committee approved these rulemaking amendments.

4. A list of all notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the exempt rulemaking:

Notice of Exempt Rulemaking: 16 A.A.R. 2282, November 26, 2010

Notice of Exempt Rulemaking: 17 A.A.R. 1767, September 2, 2011

5. The agency's contact person who can answer questions about the rulemaking:

Name: Casey Cullings

Address: Arizona Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

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6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:

The Leafy Greens Food Safety Committee administers and enforces the Arizona Leafy Green Products Shipper Marketing Agreement. This marketing agreement requires shippers of leafy green vegetables who are signatories to the agreement to follow best practices with respect to the handling of those products in order to enhance food safety and prevent the outbreak of illnesses stemming from the consumption of leafy green vegetables.

The statutes governing marketing agreements and marketing committees were recently amended by the Legislature by Laws 2011, Ch. 77. Additionally, on September 12, 2011, a four year extension of the Marketing Agreement with amendments was officially approved. The amendments took effect October 1, 2011. As a result, these rules need to be updated to take into account the recent changes to statutes and the Marketing Agreement. For example, the name of

the Committee that administers the Marketing Agreement has been changed from Leafy Green Marketing Committee to Leafy Greens Food Safety Committee.

These rules and the heading of Article 6 are being amended to take into account the new name of the Committee. Rules 601 and 602 are being updated to reflect amendments to the Marketing Agreement. Rule 603(A) is being eliminated because it is unnecessary. Revised rule 603(B) changes the use of the service mark on bills of lading from mandatory to discretionary. Rule 604(A)(4) updates the referenced section of the Marketing Agreement. Revised rule 604(F) replaces the phrase "this Section" with "subsections (B) through (D)" so that the timing of the suspension specified in this rule applies to violations of the best practices but not failures to pay assessments or misuse of the service mark. Rule 605(A) is being amended so that only violations of Rule 602 are subject to the four tiers of violation levels; therefore, other violations of the Marketing Agreement (*e.g.*, Rule 603(A)(2) and (3)) are not subject to the tiered approach of violations or progressive penalties and instead shall be subject to immediate suspension of the privilege to use the service mark. Rule 605(I) is being simplified. The Marketing Agreement and rules only refer to repeated major deviations, so there is no longer a need to say a repeated violation means a repeated major deviation.

The suspension periods in Rule 604 are also being amended to become more consistent with the California leafy green marketing agreement. Most of the signatories to the Arizona Marketing Agreement are also signatories to the California marketing agreement, and the Leafy Greens Food Safety Committee believes the two programs should generally try to mirror each other. Specifically, Rule 604(B) now sets a minimum two-week suspension instead of exactly a two-week suspension, and Rule 604(C) now provides for an indefinite suspension instead of two weeks. Both these changes copy the suspension periods listed in the California marketing agreement. These changes also give the Committee flexibility in setting the suspension period in a particular case commensurate with the seriousness of the violation and any other relevant factors. A new subsection (E) is also being added in order to take the requirement formerly found in subsection (C) about establishing and implementing a corrective action plan and to apply a similar requirement to subsections (B) through (D). The language used in new subsection (E) about undergoing an audit without any major deviations or flagrant violations comes from Article VIII(B)(2) of the Marketing Agreement and again mirrors a similar requirement in the California marketing agreement.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact, if applicable:

Not applicable

10. A description of any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and the final rulemaking package (if applicable):

Although this section is not applicable because this rulemaking is exempt from Title 41, Chapter 6, the Committee notes that two changes were made to this rulemaking at the Committee's November 29, 2011 meeting. Newly numbered rule 603(B) was amended to replace the word "shall" with "may" with respect to using the service mark on bills of lading in response to public comment that had been received. Newly numbered rule 603(F) was amended to replace the phrase "this Section" with "subsections (B) through (D)" so that the date requirements would only apply to suspensions for violations of the best practices and not the failure to pay assessments or the failure to use the mark properly.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:

Shelly A. Tunis, representing Yuma Fresh Vegetable Association, made five comments about the Committee's rules: (i) the use of parentheses in rule 602(B) makes it seem as though the words in the parentheses are lesser requirements, (ii) should the requirement in rule 603(B) to use the service mark on bills of lading be discretionary, (iii) there does not appear to be a specific length of time a suspension of the privilege to use the mark will be under rule 604(A)(2), (iv) is the suspension for nonpayment of assessments under rule 604(A)(3) longer than the time it takes to repay all past due assessments, and (v) the phrase "assessments due" in revised rule 604(I) would be better stated as "past due assessments."

The Committee responds to these comments as follows. The phrases in parentheses in rule 602(B) are already incorporated by definition into the rule, so to remove the parentheses would be to make a duplicative statement. The phrases are being added as a reminder to the signatories of current requirements, not as a new requirement. Accordingly, the Committee has determined to use the parentheses. The Committee agrees that the use of service mark on bills of lading should be discretionary and is amending the rule to reflect that. The Committee acknowledges that there is no specifically stated length of suspensions under rule 604(A)(2), which gives the Committee discretion based on the seriousness of the misuse of the mark. Members of the Committee believe that a suspension for failure to pay assessments perhaps should extend longer than the time of repayment of the past due assessments when a signa-

tory continued to use the mark while the assessments were unpaid, and the Committee plans to consider rule changes at a later time to cover this issue. The Committee is satisfied with the phrase "assessments due" in rule 604(I) and does not intend to change that language at this time.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include, but not be limited to:

The agency head of the Leafy Greens Food Safety Committee is not appointed by the Office of the Governor; therefore, Executive Order 2011-05 does not apply to this exempt rulemaking. This rulemaking would also be exempt from the rulemaking moratorium imposed by Executive Order 2011-05 by paragraph 2(g) of that Order because these rules are exempt from the rulemaking requirements of Title 41, Chapter 6 under A.R.S. § 41-1005.

A.R.S. § 3-414(C)(11) requires the Committee to provide 15 days advance notice of the meeting at which rules will be adopted and to receive public testimony at the meeting regarding the rules. The Committee complied with these requirements by giving notice on November 10 and holding the meeting on November 29. No members of the public were present at the November 29 meeting to give public testimony.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rules do not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than the federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No

13. A list of any incorporated by reference material and its location in the rule:

Rule 601: Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens: Version 5 – Arizona" dated August 1, 2011

Rule 601: Arizona Leafy Green Products Shipper Marketing Agreement, as amended effective October 1, 2011, that was approved pursuant to the Act

14. Whether the rule was previously made, amended, repealed or renumbered as an emergency rule. If so, the agency shall state where the text changed between the emergency and the exempt rulemaking packages:

Not applicable

15. The full text of the rule follows:

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

ARTICLE 6. LEAFY ~~GREEN MARKETING~~ GREENS FOOD SAFETY COMMITTEE

Section
R3-9-601. Definitions
R3-9-602. Best Practices; LGMA Compliance
R3-9-603. Service Mark Usage
R3-9-604. Loss of Use of Service Mark
R3-9-605. Violation Levels; Repeated Violations

ARTICLE 6. LEAFY ~~GREEN MARKETING~~ GREENS FOOD SAFETY COMMITTEE

R3-9-601. Definitions

"Act" means A.R.S. Title 3, Chapter 3, Article 1.

"Auditor" or "Inspector" means a state or federal agricultural regulatory agency or their designee(s), or a private entity contracted by the ~~Marketing~~ Committee to perform inspections authorized by the Act.

"Best practices" means the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens: Version 5 – Arizona" dated August 1, 2011. This document is incorporated by reference, does not include any later amendments or editions, and is available for review online at http://www.azlgma.gov/members/resources.asp and at the Arizona Department of Agriculture, 1688 W. Adams, Phoenix, Arizona 85007.

"Committee" means the Leafy Greens Food Safety Committee established pursuant to the Marketing Agreement.

"LGMA" or "Marketing Agreement" means the Arizona Leafy Green Products Shipper Marketing Agreement, as amended effective October 1, 2011, ~~dated August 29, 2007~~ that was approved pursuant to the Act. This document is incorporated by reference, does not include any later amendments or editions, and is available for review online at http://www.azlgma.gov/members/resources.asp and at the Arizona Department of Agriculture, 1688 W. Adams, Phoenix, Arizona 85007.

~~"Marketing Committee" means the Marketing Committee established pursuant to the Marketing Agreement.~~

~~"Signatory" means a shipper who has signed the Marketing Agreement.~~

"SOP" means standard operating procedure.

R3-9-602. Best Practices; LGMA Compliance

A. Signatories shall comply with the best practices, maintain a trace-back system, ~~file with the Marketing Committee reports as are periodically required,~~ and be subject to periodic ~~inspection~~ audit by an auditor.

B. Signatories shall only buy, consign, or otherwise accept or handle leafy green products (grown in Arizona) from a shipper or producer who is in compliance with the best practices (including recordkeeping requirements), maintains a trace-back system, ~~files with the Marketing Committee reports as are periodically required,~~ and is subject to periodic ~~inspection~~ audit by an auditor.

C. When the best practices require a SOP, there must be an appropriate SOP and that SOP must be followed.

R3-9-603. Service Mark Usage

~~**A.** The Marketing Committee may establish a service mark that identifies a signatory as a member in good standing of the LGMA.~~

~~**B.**~~**A.** A signatory's compliance with the LGMA and R3-9-602 is a condition precedent and subsequent to the signatory's privilege to use the service mark.

~~**C.**~~**B.** An authorized signatory ~~shall~~ may use the service mark on all bills of lading and ~~may use the service mark~~ on other documents.

~~**D.**~~**C.** A signatory shall:

1. Use the service mark without reference to a private brand or label.
2. Provide reasonable assurances that the signatory has a system in place to comply with this Section, maintain records sufficient to audit the system for the duration of the LGMA, and make those records available to the ~~Marketing~~ Committee upon request.

~~**E.**~~**D.** A signatory shall not:

1. Use the service mark on packaging or product or as a certification mark to certify product.
2. Use the service mark as the signatory's own mark or as the exclusive representation of its business entity.
3. Insert within or overlap the boundaries of the service mark with the signatory's name or trademark.
4. Alter the service mark in any way other than proportionately adjusting the size of the service mark.

R3-9-604. Loss of Use of Service Mark

A. A signatory will lose the privilege to use the service mark if the signatory:

1. Commits a flagrant violation or repeated major deviation,
2. Fails to comply with R3-9-603,
3. Has not paid assessments due for the prior fiscal year, or
4. Withdraws from participation in the LGMA pursuant to Article ~~XII, Section B~~ XVI, section C of the LGMA.

B. The first flagrant violation or repeated major deviation will result in a ~~two-week~~ suspension of the privilege to use the service mark for a minimum two-week period.

C. A flagrant violation or repeated major deviation following the first flagrant violation or repeated major deviation will result in ~~a~~ an indefinite suspension of the privilege to use the service mark ~~for two weeks or until the signatory has established and implemented a corrective action plan approved by the auditor and the Marketing Committee, whichever is longer~~.

D. A flagrant violation or repeated major deviation following a suspension pursuant to subsection (C) will result in an indefinite revocation of the privilege to use the service mark. The privilege to use the service mark will not be restored to the signatory for a minimum of two years unless the signatory demonstrates to the satisfaction of the auditor and the ~~Marketing~~ Committee a significant change in management and brand.

E. A signatory whose privilege to use the service mark is suspended or revoked pursuant to subsections (B) through (D) shall not use the service mark until the signatory has undergone at least one new audit without the finding of any major deviations or flagrant violations and has evidenced that the signatory has corrected any minor deviations found.

~~**F.**~~**F.** At least two weeks of any suspension of the privilege to use the service mark under ~~this Section~~ subsections (B) through (D) must occur between December 1 and March 31.

~~**F.**~~**G.** The ~~Marketing~~ Committee may accelerate the progression of penalties under this Section if the signatory's product seriously affects a person's health and the signatory handled the product with intentional, knowing or reckless disregard for

the signatory's obligations under the LGMA and best practices.

~~G.~~**H.** A signatory will not lose the privilege to use the service mark under subsection (A)(1) and (2) without an opportunity for a hearing under A.R.S. Title 41, Chapter 6, Article 10, except if the ~~Marketing~~ Committee finds that the public health, safety or welfare imperatively requires emergency action, and incorporates a finding to that effect in its order, the ~~Marketing~~ Committee may order summary suspension of a signatory's privilege to use the service mark.

~~H.~~**I.** A signatory that loses the privilege to use the mark under subsection (A)(3) must pay all assessments due from prior fiscal years, including penalties and interest, before regaining the privilege to use the service mark.

~~I.~~**J.** The ~~Marketing~~ Committee may publish a list of signatories whose privilege to use the service mark has been suspended.

R3-9-605. Violation Levels; Repeated Violations

A. Violations of ~~the LGMA and~~ R3-9-602 fall into four levels: flagrant violations, major deviations, minor deviations, and minor infractions. The ~~Marketing~~ Committee or its designee shall determine the level of a violation consistent with this Section.

B. A flagrant violation occurs when a signatory buys, consigns, or otherwise accepts or handles a leafy green product and knows or should have known the product was grown, packed, shipped, processed or handled in violation of R3-9-602 and the violation:
1. Significantly increases the risk of delivering unsafe product into commerce;
2. Affects the integrity of the LGMA's food safety program; or
3. In the ~~Marketing~~ Committee's judgment, merits more serious treatment than a major deviation based on the consideration of, as relevant:
   a. The position of the employee responsible for the violation;
   b. Whether the employee responsible for the violation knowingly committed the violation;
   c. The circumstances surrounding the violation;
   d. Whether the signatory took prompt corrective action;
   e. Whether the signatory has committed the same or a similar violation previously; and
   f. Any other relevant facts.

C. A major deviation is a violation of R3-9-602 that may inhibit the maintenance of food safety, but that does not necessarily result in unsafe product.

D. The following violations constitute at least major deviations and are potentially flagrant violations:
1. Falsification of any record for any reason;
2. Spitting in the field;
3. Unclean sanitation facilities, including the presence of soiled toilet paper;
4. Failure to:
   a. Properly wash hands after using a restroom or returning to the field;
   b. Follow the best practices with respect to feces or fecal matter found in the field;
   c. Follow the best practices with respect to the use of compost or animal manure, including creating and maintaining proper records related to that use;
   d. Have a trace-back system;
   e. Sanitize gloves and knifes;
   f. Follow a work health practices program concerning the transfer of human pathogens by workers; or
   g. Provide a Compliance Plan, as defined in the best practices, to an auditor;
5. Refusing an audit; and
6. Conditions for which an automatic "unsatisfactory" would be assessed by USDA if performing a GAP/GHP audit.

E. Violations constituting flagrant violations or major deviations are not limited to those listed in ~~paragraph D~~ subsection (D).

F. A minor deviation is a violation of R3-9-602 that the signatory can correct within five business days of the audit and that does not necessarily increase the risk of a food borne illness.

G. A minor infraction is a violation of R3-9-602 that the signatory corrects before the auditor leaves the audited premises and that does not necessarily increase the risk of a food borne illness.

H. The Marketing Committee or its designee may assess a signatory with a major deviation if an auditor discovers several minor deviations or minor infractions of the same type or if a signatory fails to timely submit a corrective action plan.

I. ~~A repeated violation under the LGMA and this Article only occurs when the violations at issue are major deviations.~~ Repeated major violations are limited to violations occurring during the current and prior fiscal year.